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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/795,835	03/09/2004	John P. Cole	030504	1237

43831 7590 01/04/2006

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EXAMINER

NGUYEN, VI X

ART UNIT PAPER NUMBER

3731

DATE MAILED: 01/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

<b>Office Action Summary</b>	<b>Application No.</b> 10/795,835	<b>Applicant(s)</b> COLE, JOHN P.	
	<b>Examiner</b> Victor X. Nguyen	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 October 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-32 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-29 is/are allowed.
- 6) ☐ Claim(s) 30 and 31 is/are rejected.
- 7) ☒ Claim(s) 32 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/05</u> . | 6) <input type="checkbox"/> Other: _____  |

DETAILED ACTION

*Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: -

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 30-31 are rejected under 35 U.S.C. 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. 103 (a) as obvious over Kraus (6,641,564).

Kraus discloses in figures 3,5 and 7-8, a surgical device having the limitations as recited in the above listed claims, including: a nipple end portion 142 has a bore disposed therethrough, a tubular punch means 120 is in the form of a hollow cylinder, where the tubular punch means being slidably disposed within the bore, a means 134 for adjusting the position of the tubular punch means within the bore. Regarding claim 30, the device could make the tubular punch means including an inner diameter between 0.5 and 4.5 millimeters and the total surface area of the nipple end which contacts the patient is in the range of between about 5 square millimeters and about 25 square millimeters. In the alternative, it has been held that changes in size only require routine skill in the art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the device with the tubular punch means including an inner diameter between 0.5 and 4.5 millimeters and the total surface area of the nipple end which contacts the patient is in the range of between about 5 square millimeters and about 25 square millimeters and a minor modification of Kraus' device would adopt the same for use under various conditions of service, since it has been held that where the general

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conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re. Aller*, 220F, 2d 454, 105 USPQ 233. *See In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

***Allowable Subject Matter***

2. Claims 1-29 are allowed.

Claim 32 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is an examiner's statement of reasons for allowance: None of the prior art of records disclose or suggest, where a tubular punch means has a sharp end portion which is in a hollow cylinder form, where the tubular punch means is slidably disposed within a second bore, where a stabilizer means disposed within a first bore and in contact with the tubular punch means, and where an adjustment screw comprises a head portion, a threaded outer surface that is disposed within the first bore such that its threaded outer surface is in effective mechanical contact with the inner surface within a main body, where the adjustment screw is disposed to be in selectively contactable with the tubular punch means.

***Response to Arguments***

3. Applicant's arguments with respect to claims 1 and 30 have been considered but are moot in view of the new ground(s) of rejection. Applicant is asked to refer to the modified prior art rejection above where examiner addresses applicant's concerns regarding prior art rejection.

***Conclusion***

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X. Nguyen whose telephone number is (571) 272-4699. The examiner can normally be reached on M-F (8-4.30 P.M).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Victor X Nguyen  
Examiner  
Art Unit 3731

Vn VN  
12/23/2005



**JULIAN W. WOO**  
**PRIMARY EXAMINER**